Trauma System

ARTIS™ / ARMAR™ / DHUM™ / KET™ | Bone Plates

ACCURA™/CLAVO™/KET™ | Nails

FIXION™ / MBOSS™ / DHUM™ / KET™ | Bone Screws

EN

CE 2195

Carefully read all instructions and be familiar with the surgical techniques prior to use.

℞ NON STERILE

Introduction

Bone plates are thin metal plates used to reconstruct a bone that has been fractured. They immobilize the bone segments. For severe fractures, bone plates are surgically implanted to hold the bone in place. The plate is affixed with screws to properly align the bone and aid in the healing process.

Bone Screws are used for internal fixation and can be used alone to hold a fracture, as well as with plates or nails.

Nail is a metal rod used to hold the bone pieces together especially in long bone fracture through the hollow center of the bone that normally contains some marrow. Screws at each end of the nail are used to keep the fracture from shortening or rotating, and also hold the nail in place until the fracture has healed.

Meril supplies clean, but non-sterile trauma implants Bone plates, bone screws and Nails. These implant must undergo under sterilization process before use by the health care provider in order to render the device STERILE prior to implantation.

Intended Use

ARTIS™ / ARMAR™/DHUM™/KET™ - Bone Plates:

The bone plates are provided non-sterile in a tray or separately packed. The devices are intended to treat fractures of various bones, including the clavicle, scapula, pelvis, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, and phalanges).

Bone plates are mostly used in:

- spine fixation
- orthopaedic fracture applications
- atrophic fracture
- humeral, ankle and finger plate systems
- Musculoskeletal surgery
- Olecranon Fractures
- **ACCURA™/CLAVO™/KET™- Nails:**

  An intramedullary rod, also known as an intramedullary nail (IM nail) is a metal rod forced into the medullary cavity of a bone. IM nails have long been used to treat fractures of long bones of the body.

  The Intramedullary Nail (IM Nail) is intended for use in the fixation of long bone fractures, including diaphyseal fractures in the humerus, tibia and femur. It is indicated for shaft fractures 5cm below the surgical neck, and 5cm proximal to the distal end of the medullary canal.

  FIXION™ / MBOSS™/ DHUM™ / KET™ - Bone Screws:

  A bone screw is a metal implant inserted into the bone. Screws are used to immobilize fractured bone segments to aid in the healing process. Following are some uses of Bone screws
- Repair of bone fracture by osteosynthesis
- Fixation of bone fragments in bone grafting
- Fixation of bone fragments in osteotomy
- Fixation of bone fragments in reconstructive procedures
- Fixation of ligaments or soft tissues

Materials

Products	Materials Grade
ARTIS™ / ARMAR™/DHUM™/KET™ - Bone Plates:	SS316LVM (Stainless steel) TiCP (Titanium Commercial Pure), Grade 4 TAN (Titanium-6Aluminium-7Niobium Alloy)
ACCURA™/CLAVO™/KET™ - Nails:	SS316LVM (Stainless steel) TAN (Titanium-6Aluminium-7Niobium Alloy)
FIXION™ / MBOSS™/ DHUM™ / KET™ - Bone Screws:	SS316LVM (Stainless steel) TiCP (Titanium Commercial Pure), Grade 4 TAN (Titanium-6Aluminium-7Niobium Alloy)

Disclaimer

Meril has verified through laboratory testing that certain of its implantable devices are suitable for the specific sterilization methods and cycles for which they have been tested. Health care personnel bear the ultimate responsibility for ensuring that any particular packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that requirements and conditions essential to sterilization can be achieved. In the event that health care personnel fail to properly sterilize the device as required, Meril does not accept responsibility or liability for any damages or otherwise arising from a lack of sterility of an implantable device supplied in a clean but non-sterile condition.

Cleaning And Decontamination

Non-sterile trauma implantable devices are supplied in a cleaned condition in clean packaging materials. Further cleaning other than sterilization is not required. **Use care in handling a device once the device is removed from the packaging in order to prevent any inadvertent contamination, damage, or otherwise jeopardize the integrity of the device.**

General

Hospital / Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance. DO NOT ATTEMPT TO STERILIZE THE DEVICE IN THE PACKAGING MATERIALS SUPPLIED.

Sterility

Implantable devices supplied by Meril have been cleaned and inspected. Unless otherwise indicated, these devices are not sterile and must be sterilized prior to use.

Trauma implants can be steam autoclaved, and repeated autoclaving will not adversely affect them, unless otherwise indicated on the labeling. Implantable devices may be autoclaved using a full cycle.

Users should conduct testing in the health care facility to ensure that the conditions essential to sterilization can be achieved and are acceptable for the steam sterilization process. For non-sterile implants remove all original packaging and labeling inserts prior to sterilization. ANSI/AAMI ST46 Steam sterilization and Sterility Assurance in Health Care Facilities provides guidelines for design and personnel considerations, processing recommendations, care of sterilizers, quality control, and quality process improvement.

Set forth below is a recommended minimum cycle for steam sterilization that has been validated by Meril under laboratory conditions. Individual users must validate the steam autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters described below.

Pre-Vacuumed Sterilizer (HI-VAC)

270° - 275° F (132° - 135° C) - Double or Single wrapped - 4-minutes exposure time, 8-minutes drying time

Since Meril is unfamiliar with individual hospital handling procedures and other conditions, Meril assumes no responsibility for sterilization of any product or device by a hospital or medical care facility even if the general above guidelines are followed..

Storage and Shelf Life

Implantable devices that have been wrapped to maintain sterility should be stored in a constant, well- regulated environment for temperature and humidity. Devices should not be subject to environmental extremes including temperature and moisture. Care must be exercised in the handling of wrapped devices to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped devices based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event related and that the probability of a contaminating event increases over time, with handling, and whether woven or nonwoven materials, pouches, or container systems are used as the packaging method.

Warnings And Precautions

1. The implantable devices are supplied non sterile and must be sterilized prior to implantation.
2. Implantable devices should not be flash-autoclaved. Unwrapped implantable devices don't maintain sterility.
3. Do not reuse implant as it may lead to an increased risk of contamination / infection.
4. The implant shall be used by trained professionals / orthopedic surgeons only.
5. The patient should not enter in electromagnetic area.
6. The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
7. Because of unbalanced muscle forces, sub trochanteric fractures and osteotomies place extreme loads on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.
8. Length of plate must allow engagement of the maximum number of cortical screws in the intact femoral shaft distal to the fracture line. The length of time for non- or limited weight bearing should be correspondingly increased until solid bony union occurs.
9. The threads of an implanted lag screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
10. Use only stainless steel screws, nails or plates with stainless steel devices.

Contraindications

1. Active Infection.
2. Conditions which tend to retard healing such as blood supply limitations previous infections.
3. Insufficient quantity or quality of bone to permit stabilization of the osteotomy.
4. Lack of musculo-cutaneous cover.
5. Muscular deficit, neurological deficiency or behavioral disorders which could submit the osteosynthesis to abnormal mechanical strains.
6. Cases with malignant primary or metastalic; tumors which preclude adequate bone support or screw fixations.
7. Very proximal or distal fractures, highly comminuted fractures and longitudinal splits or longitudinal fractures for nail fixations.
8. Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process.
9. Foreign body sensitivity

MRI Safety Information

The Trauma system- Bone Plates has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Trauma system- Bone Plates in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Meril

Orthopedics

Meril Healthcare Pvt. Ltd.
First Floor, H1-H3, Meril Park
Survey No.135/2/B & 174/2
Muktanand Marg, Chala
Vapi - 396191, Gujarat, India.
T+91 260 3052100
F+91 260 3052125

EC REP OBELIS S.A
Bd. Général Wahis, 53
1030 Brussels, Belgium
T +32.2.732.59.54
F +32.2.732.60.03
E mail@obelis.net, W www.obelis.net

Consult Instructions For Use | Do Not Reuse | Do not use if Package is Damaged | Keep Dry | Keep Away from Sunlight

Rev. 04
Rev. D: 2020-07
MH/IFU/TS/020